Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 331—ANTACID PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

PART 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

Final Order for Antacid and Antiflatulent Products Generally Recognized as Safe and Effective and Not Misbranded

Pursuant to procedures promulgated in the FEDERAL REGISTER of May 11, 1972 (37 FR 9464), a review of the safety and effectiveness of over-the-counter (OTC) antacid drugs has been undertaken by the Food and Drug Administration.

Notice inviting submission of data and information, published and unpublished, and other information pertinent to the safety and effectiveness of OTC antacid products was published in the FEDERAL REGISTER of January 5, 1972 (37 FR 102). An additional period was allowed for submission of such data and information in paragraph 18 of the preamble to the final procedural regulations published in the FEDERAL REGISTER of January 5, 1972 May 11, 1972 (37 FR 9464).

The conclusions and recommendations of the OTC Antacid Drug Panel and a proposed monograph for OTC antacid drugs was published in the FEDERAL REGISTER of April 5, 1973 (38 FR 8714). A tentative final order pertaining to monographs for OTC antacid and OTC antiflatulent products was published in the FEDERAL REGISTER of November 12, 1973 (38 FR 31260). Notice of a public hearing on the November 12, 1973 tentative final order was published in the FEDERAL REGISTER of January 8, 1974 (39 FR 1359), and the public hearing was held on January 21, 1974. A revision of the November 12, 1973 tentative final order containing a modification of the antacid in vitro test was published in the FEDERAL REGISTER of January 22, 1974 (39 FR 2488).

In addition, a notice of proposed rule making to establish general conditions for OTC drugs listed as generally recognized as safe and effective and as not misbranded was published in the FEDERAL REGISTER of April 5, 1973 (38 FR 8714). The final order on this proposal was published in the FEDERAL REGISTER of November 12, 1973 (38 FR 31258) and became effective on December 12, 1973.

In view of the fact that the regulations for drugs for human use were recodified in the FEDERAL REGISTER of March 29, 1974 (39 FR 11680), the following preamble will identify, as necessary, both prior and current designations for the convenience of the reader.

Objections and requests for a hearing on the tentative final order were submitted by a number of persons. On January 21, 1974, the Commissioner of Food and Drugs held a public hearing to receive oral and written statements on the tentative final order. At the hearing, the Commissioner stated that he would allow 10 days for parties to submit any additional written comments to the Hearing Clerk on any of the hearing issues except that 30 days would be allowed for comments on the proposed effective date of the final order.

The Commissioner stated at the public hearing that the in vitro test in the tentative final order required revision. The test was republished in the FEDERAL REGISTER of January 22, 1974 (39 FR 2488) as a new tentative final order, with further opportunity for objections and/or requests for a public hearing on this aspect of the matter. Nine objections were received on the revised in vitro test. One request for a hearing on the revised test was made, but was subsequently withdrawn.

The Commissioner has reviewed all written and oral comments including the objections filed, the hearing record, and all other comments, pertaining to the tentative final order. Where pertinent, the Commissioner has also again reviewed the scientific information contained in the record of this proceeding. The Commissioner has reached the following conclusions and decisions.

GENERAL COMMENTS

1. There were numerous comments that the antacid monograph should be interpretive, not substantive.

The Commissioner dealt with this issue in paragraphs 85 to 91 of the preamble to the final order establishing the procedures for the OTC drug review published in the FEDERAL REGISTER of May 11, 1972 (37 FR 9464) and paragraph 3 of the preamble to the tentative final order for OTC antacid drugs published in the FEDERAL REGISTER of November 12, 1973 (38 FR 31260). No new points were presented in the comments, and the Commissioner reaffirms the earlier statements. Every court which has to this time considered the issue has found in favor of the substantive application of the OTC drug monographs. The new monographs will be enforceable regulations requiring uniform compliance. The alternative would serve to negate the entire review process. A direct challenge to the legal authority of the Food and Drug Administration to promulgate substantive OTC drug monographs has recently been dismissed in Smart v. Food and Drug Administration (N.D. Calif., C-73-0118-RHS, April 24, 1974), and a second court has also held that section 701(a) of the act authorizes substantive rulemaking, National Nutritional Foods Association v. Weinberger (S.D. N.Y., 73 Civ 3448, April 5, 1974).

2. There were comments that a fuller description of the panel meetings (summary minutes) and/or the transcripts of the panel meetings should be made available.

The Commissioner dealt with this matter in paragraph 37 of the preamble to the final regulation establishing the OTC drug review procedures, published in the FEDERAL REGISTER of May 11, 1972 (37 FR 9464) and paragraph 8 of the preamble to the November tentative final order. The Commissioner has concluded that, when viewed in light of the report and data on file with the Hearing Clerk, the minutes amply serve their intended purpose and the transcript of the closed portion of the Panel meetings should not be made public.

Some of the comments reflected an erroneous impression about the role of a panel in the OTC drug review. Pursuant to section 9(b) of the Federal Advisory Committee Act, the OTC drug review panels are utilized solely for advisory functions. Determinations of action to be taken and policy to be expressed with respect to matters upon which an advisory committee reports or makes recommendations to the Food and Drug Administration must be made solely by the Commissioner. Once the panel has issued its report, its advisory functions are completed. Thus, the purpose of the summary minutes is to maintain a full and accurate record of the panel's reasoning and judgments and to minimize the circulation of speculative and misleading information as to the current status of the review. They constitute part of the public record in order to assist any interested person in formulating meaningful comment on the panel report and the proposed monograph. They have no independent substantive status.

Once the panel has issued its report to the Commissioner, it is the legal responsibility of the Commissioner to review and evaluate it, and to issue a proposed order, tentative final order, and final order reflecting his own conclusions and decisions. This responsibility is independent of the recommendations contained in the panel minutes and report, and it is possible that the Commissioner may adopt conclusions and make decisions contrary to a panel's recommendations.

The transcripts of all open portions of the Antacid Panel meetings are available at cost from the recording company. The Commissioner has concluded that the transcripts of closed portions of the panel meetings should not be released. This conclusion was recently upheld in Smart v. Food and Drug Administration, supra, in which the United States District Court for the Northern District of California held that the deliberative portions of the Antacid Panel were properly closed to the public and that the transcripts of those portions are confidential and are not required to be released under the Freedom of Information Act or the Federal Advisory Committee Act.

The legal justification for closing the deliberative portion of the Antacid Panel's discussions—i.e., the discussion during which the Panel determined its conclusions and recommendations—and retaining the transcripts of those closed portions as confidential may be found in section 10 of the Federal Advisory Committee Act and exemption (5) of the Freedom of Information Act. Section 10(a)(1) of the Federal Advisory Committee Act provides that each advisory

per minimum time interval. For compliance purposes, the value determined by the acid neutralizing test at any point in time shall be at least 90 percent of the labeled value. No product shall be marketed with an acid neutralizing capacity below 5 mEq.

(2) May contain an indication for the symptomatic relief of hyperacidity associated with the diagnosis of peptic ulcer, gastritis, peptic esophagitis, gastric hyperacidity, and hiatal hernia.

(b) Professional labeling for an antacid-antiflatulent combination may contain the information allowed for health professionals for antacids and antiflatulents.

PART 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

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Subpart A—General Provisions

§ 332.1 Scope.

An over-the-counter antiflatulent product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the following conditions and each of the general conditions established in § 330.1 of this chapter.

Subpart B—Active Ingredients

§ 332.10 Antiflatulent active ingredients.

Simethicone; maximum daily dose 500 mg. There is no dosage limitation at this time for professional labeling.

§ 332.15 Combination with non-antiflatulent active ingredients.

An antiflatulent may contain any generally recognized as safe and effective antacid ingredient(s) if it is indicated for use solely for the concurrent symptoms of gas associated with heartburn, sour stomach or acid indigestion.

Subpart C—[Reserved]

Subpart D—Labeling

§ 332.30 Labeling of antiflatulent products.

(a) *Indications.* The labeling of the product represents or suggests the product as an "antiflatulent" and/or "to alleviate or relieve the symptoms of gas."

(b) *Directions for use.* The labeling of the product contains the recommended dosage per time interval (e.g., every 4 hours) or time period (e.g., 4 times a day) broken down by age groups if appropriate, followed by "except under the advice and supervision of a physician." The words "or as needed" may be used after the recommended dosage per time interval or time period.

§ 332.31 Professional labeling.

(a) The labeling of the product provided to health professionals (but not to the general public) may contain as additional indications postoperative gas pain or for use in endoscopic examination.

(b) Professional labeling for an antiflatulent-antacid combination may contain information allowed for health professionals for antacids and antiflatulents.

Effective date. This order shall become effective on July 5, 1974, except that all labeling for products not receiving an extension of the effective date for reformulation shall become effective on June 4, 1975, and where reformulation is necessary and an extension is granted shall become effective on June 4, 1976. The labeling of a product to health professionals shall after June 4, 1976, contain the neutralizing capacity of the product as calculated using the procedure set forth in § 331.26.

Dated: May 29, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

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